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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard Gallo

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CANADA

EXAMINER

ALIKHANI, SHADI

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,118	Applicant(s) GALLO ET AL.	
	Examiner SHADI ALIKHANI	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/29/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04/29/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 04/29/2005.
2. Claims 3, 5, 7-8, 10-13, 15, and 17-18 have been amended.
3. Claims 1-18 are currently pending and have been examined.

Claim Objections

4. Claim 13 is objected to because of the following informalities: the applicant discloses "...and creep properties temperatures encountered in a human body." Did the applicant mean to say "...and creep properties when temperatures encountered in a human body?" Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5, 8-13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Willard et al. (US 5,980,530).

Claims 1-3, 5, 8-13, 15-18:

Willard et al. as shown disclose the following limitations:

- *an armature (Fig. 4, #20) made in a first material allowing an expansion over time of said armature (col. 3, ln 12-18);*
- *a matrix (Fig. 4, #34) made in a second material, said matrix being added on said armature (col. 2, ln 8-25);*

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- *said second material is selected in the group consisting of polycarbonate and polyethylene (col. 3, ln 61).*

Polyethylene inherently exhibits a gradual, slow, and irreversible plastic deformation and creeping behavior (expansion in this case) in response to load and temperature, such as force exerted by a balloon catheter when being inflated or by the body temperature. The examiner asserts that the following claimed physical properties are therefore present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that the following properties are not present in the prior art.

Accordingly, Willard et al. disclose the limitations as shown above and further disclose plastic reinforcing rings or matrix made out of polyethylene, which securely retain, restrict, and hold the self-expanding stent to the balloon in a pre-deployed state, after which balloon inflation causes the stent to expand gradually (col. 2, ln 8-25; col. 3, ln 65). Willard et al. thus further disclose the following limitations:

- *said second material gradually loses mechanical properties thereof by creeping, after the stent is deployed under a deployment of a balloon introduced into said armature, thereby allowing a controlled radial expansion of said armature over a period of time (col. 2, ln 8-25; col. 3, ln 65).*
- *said second material loses the mechanical properties thereof at a temperature encountered in a human body.*
- *said second material includes at least in part polymeric materials (col. 3, ln 61), said second material having an initial rigidity sufficient to maintain the stent in a contracted position on the balloon during storage (col. 3, ln 54), a low yield strain from an elastic to a plastic regime, a sufficiently high total elongation, and creeping properties at human body temperature.*
- *said matrix comprises a number of rings (see Fig. 4, #34).*
- *said first material is a shape memory alloy (col. 3, ln 17-18).*
- *said shape memory alloy is nitinol (col. 3, ln 17-18).*

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- *said stent (20), including said matrix (34), mounted on the balloon, is introduced into a retention sheath (Fig. 4, #22; col. 2, ln 1-4) preventing a creep of said matrix during storage of the stent (see Fig. 4), thereby preventing a deployment of the armature (col. 2, ln 8-12).*

Willard et al. discloses the limitations as shown above and accordingly discloses an apparatus to perform the method of:

- *introducing in the lumen a stent comprising an armature (Fig. 4, #20) made in a first material (col. 3, ln 12-18) allowing self-deployment of the armature (col. 3, ln 12-18); and*
- *a matrix (Fig. 4, #34) made in a second material having creep properties that make it gradually lose mechanical properties thereof (col. 2, ln 8-25);*
- *deploying the armature using a balloon positioned in the armature (col. 2, ln 8-25); the balloon ensuring a substantially irreversible deformation of the matrix during inflation of the balloon and allowing a self- deployment of the armature; and*
- *removing the balloon from the lumen (col. 1, ln 21-24); whereby the creep properties of the second material (or polyethylene) allow the progressive self-deployment of the armature (col. 3, ln 12-18); and a positioning of the armature at a predetermined position in the lumen (col. 1, ln 64-67) with minimized damage on walls of the lumen (col. 3, ln 12-18).*
- *the second material includes at least in part polymeric materials (col. 3, ln 61), and has an initial rigidity sufficient to maintain the stent in a contracted position on the balloon during storage (col. 3, ln 54), a low yield strain from an elastic to a plastic regime, a sufficiently high total elongation, and creep properties temperatures encountered in a human body.*
- *removing the stent from a retention sheath (22) covering the matrix (Fig. 4, #34 col. 2, ln 1-2 and 8-26) and the armature (20) before introducing the stent in the lumen (col. 2, ln 64-67; col. 3, ln 8-26).*

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Willard et al. (US 5,980,530) in view of Lau et al. (US 5,873,906).

Claims 6-7:

Willard et al. disclose the limitations as shown above and further disclose that the rings (34) are wound around the stent. Willard et al. do not explicitly disclose the following limitations, but Lau et al. as shown do:

- *said rings are selected in the group consisting of rings braided (Fig. 3, #124) around said armature (see Fig. 3) and rings secured in slots provided on said armature.*
- *said matrix includes a coating deposited on said armature (col. 5, ln 53-55)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Willard's rings to include a braided configuration around the stent, because "...the linked helical stent structure used in the stent-graft provides a good combination of radial strength and flexibility." (col. 2, ln 36-38)

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10. Claims 4 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Willard et al. (US 5,980,530) in view of Latour et al. (NPL CCC 0021-9304/98/020214-10).

Claims 4 and 14:

Willard et al. disclose the limitations as shown above, and further disclose that the stent is made up of Nitinol and the ring is made up of polyethylene. Willard et al. do not explicitly disclose that:

- *the initial rigidity of said second material is at least 1000 MPa, the yield strain thereof is less than about 8%, the total elongation thereof is greater than about 100 %, and the creeping properties thereof allow a loss of at least 50% of the Initial rigidity thereof within 1000 hours.*
- *the initial rigidity of the second material is at least 1000 MPa, the yield strain thereof is less than about 8%, the total elongation thereof is at least about 100 % and the creep properties thereof allow a loss of at least 50% of the initial rigidity within 1000 hours.*

However, Latour et al. disclose a polyethylene material and its properties such as “compressive creep at 37°C” and rigidity of 600 MPa – 4 Gpa, as well as a decrease in rigidity due to creep for up to 250 hours, 30 days, and 110 days, and concluded that there is a relationship between creep resistance and temperature, amount of load, period of loading, and the molecular weight and structural compositions of polyethylene. Latour et al. also disclose that most of the creep of a polymer takes place during loading in early periods of implantation.

Latour et al. disclose the limitations as shown above, but do not explicitly disclose that *the initial rigidity of the second material is at least 1000 MPa, the yield strain thereof is less than about 8%, the total elongation thereof is at least about 100 % and the creep properties thereof allow a loss of at least 50% of the initial rigidity within 1000 hours.* It would have been obvious to one of ordinary skill in the art at the time of the invention to include an initial rigidity of 1000 Mpa, a yield strain of less than 8%, a total elongation of 100%, and 50% loss of rigidity within 1000

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hours, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d, 205 USPQ 215 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHADI ALIKHANI whose telephone number is (571)270-5305. The examiner can normally be reached on Monday - Thursday 10AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shadi Alikhani

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/Shadi Alikhani/
Examiner, Art Unit 3734